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EXAMINER

NEGIN, RUSSELL SCOTT

ART UNIT	PAPER NUMBER
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1631

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/561,889	Applicant(s) SAYOOD ET AL.	
	Examiner Russell S. Negin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,15,17-19 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,15,17-19 and 21-31 is/are rejected.
- 7) ☒ Claim(s) 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Comments

Applicant's amendments and request for reconsideration in the communication filed on 27 July 2010 are acknowledged and the amendments are entered.

Claims 1, 3-11, 15, 17-19, and 21-31 are pending in the instant application.

Claims 1, 3-11, 15, 17-19, and 21-31 are examined in this Office action.

Oath/Declaration

The following OBJECTION is reiterated:

The declaration filed on 6 September 2005 is defective because all of the copies of the declaration do not list each inventor. In this instance, the copy of the oath signed by Khalid Sayood does not include the name of the third inventor, Steven H. Hinrichs. See MPEP 201.03 II B and MPEP 605.04(a) for rules governing the signatures and listing of inventors on oaths and declarations submitted for an invention.

Response to arguments:

Applicant's arguments filed 27 July 2010 have been fully considered but they are not persuasive.

While applicant asserts that all three inventors were present on the copies of the declaration, this assertion is not supported by the re-submitted document. MPEP section 201.03 subsection II B even gives the example:

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An oath or declaration under 37 CFR 1.63 by each actual inventor must be presented. While each inventor need not execute the same oath or declaration, each oath or declaration executed by an inventor must contain a complete listing of all inventors so as to clearly indicate what each inventor believes to be the appropriate inventive entity. Where individual declarations are executed, they must be submitted as individual declarations rather than combined into one declaration. For example, where the inventive entity is A and B, a declaration may not be executed only by A naming only A as the inventor and a different declaration may not be executed only by B naming only B as the inventor, which two declarations are then combined into one declaration with a first page of boiler plate, a second page with A's signature, and a second page with B's signature (so that it appears that the declaration was executed with the entire inventive entity appearing in the declaration when it did not).

Consequently, using this fact pattern, there is no support that the copy of the declaration signed by Khalid Sayood had the same of the third inventor, Steven H. Hinrichs.

Priority

It is noted that while the declaration filed on 6 September 2006 claims benefit to provisional application 60/479,668 filed on 19 June 2003, this benefit claim is now proper. Accordingly, claims 1, 3-11, 15, 17-19, and 21-31 receive the benefit date of 19 June 2003.

Claim Objections

Claim 31 is objected to because of the following informalities:

Line 3 of claim 31 recites "that satisfies triangle inequality" which should read "that satisfies ***the*** triangle inequality".

Appropriate correction is required.

Withdrawn Rejections

The rejections of claims 1-9, 11-17, and 19-21 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter are withdrawn in view of amendments filed to the instant set of claims on 27 July 2010.

The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of amendments filed to the instant claim on 27 July 2010.

The rejections of claims 7-9 and 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of arguments on page 11 of the Remarks.

The rejections of claims 1-6, 10-16, and 18-21 under 35 U.S.C. 102(b) as being anticipated by Varre et al. [Bioinformatics, volume 15, 1999, pages 194-202] are withdrawn in view of amendments filed to the instant set of claims on 27 July 2010.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following rejection is reiterated:

Claims 10, 18, and 22-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 10, 18, and 22-23 are drawn to storage media for understanding and determining the presences of nucleotides within sequences, or determining distances between sequences of nucleotides within a bigger sequence.

While lines 6-14 of page 3 of the specification disclose that the algorithm can be performed on a “universal computer,” the specification is silent on what comprises the recited computer readable storage media. Consequently, in the absence of such a disclosure, computer readable storage media are interpreted to encompass carrier waves, which, per se, are not statutory.

Response to Arguments:

Applicant's arguments filed 27 July 2010 have been fully considered but they are not persuasive.

Applicant argues that the amended claims overcome the rejections of record. This argument is not persuasive because the rejected claims still encompass carrier waves. Applicant is encouraged to refer to Volume 1351, page 212 of the Official Gazette of the USPTO for further guidance on subject matter eligibility of computer readable media.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following rejection is necessitated by amendment:

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INDEFINITENESS

Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 29, it is unclear if it is the sum of the first and second numbers that is divided by the number of words OR if it is only the second number that is divided by the number of words that is needed to build the third nucleic acid sequence. For the purpose of examination, it is interpreted that the sum is divided by the number of words.

In claim 30, it is unclear if it is the sum of the first and second numbers that is divided by the average of a third and fourth number of words OR if it is only the second number that is divided by the average. For the purpose of examination, it is interpreted that the sum is divided by the average.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following rejection is reiterated for claim 7-9, 17, and 22-23 and is necessitated by amendment for claims 1, 3-6, 10-11, 15, 18, 19, and 21:

35 U.S.C. 103 Rejection #1:

Claims 1, 3-11, 15, 17-19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varre et al. [Bioinformatics, volume 15, 1999, pages 194-202] in further view of Queen et al. [Nucleic Acids Research, Volume 12, 1984, pages 581-599].

Discussion of Independent claims 1, 10, 11, 18, 19, and 21-23:

Independent claim 1 is drawn to a computer-implemented method of determining whether a set of nucleotides is within a first nucleic acid sequence. The method comprises receiving a first and a second nucleotide of a second nucleic acid sequence wherein the second nucleotide is after the first nucleotide. The method also comprises combining the first and second nucleotide sequence into a first set of nucleotides. The method also comprises comparing (at a computer) the first set of nucleotides to a first nucleic acid sequence to determine whether the first set of sequential nucleotides is within the first nucleic acid sequence. Claim 1 also requires that if the first set of nucleotides is not within the first nucleic acid sequence, storing the first set of

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nucleotides as a unit in a database in one or more storage devices for the second nucleic acid sequence.

Independent claim 10 is drawn to similar subject matter as claim 1, except claim 10 takes the form a computer storage media rather than a method.

Independent claim 11 is drawn to similar subject matter as claim 1 and additionally creates a database of nucleotide units for a first nucleic acid sequence. The method comprises receiving a first nucleotide of a first nucleic acid sequence, determining whether the first nucleotide has been stored in a database as a unit for the first nucleic acid sequence, and if not, storing the first nucleotide as a storing the first nucleotide as a unit for the first nucleic acid sequence.

Independent claim 18 is drawn to similar subject matter as claim 11, except claim 10 takes the form a computer storage media rather than a method.

Independent claim 19 is drawn to similar subject matter as independent claim 1, except as a system and not a method.

Independent claim 22 is drawn to a method of determining the distance between two nucleic acid sequences. The method comprises determining the number of words in a first nucleic acid sequence. The method also comprises combining the first sequence with a second nucleic acid sequence to make a combined nucleic acid sequence. The method also comprises determining the number of words in the combined nucleic acid sequence. The method also comprises determining the difference between the number of words in the combined nucleic acid sequence and the

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first nucleic acid sequence to determine the distance between the first nucleic acid sequence and the second nucleic acid sequence.

Independent claim 23 is drawn to similar subject matter as independent claim 22, except as a system and not a method.

The article of Varre et al. studies determining distances using a family of dissimilarity measures in oligonucleotide sequences [title].

Specifically, Figure 1 on page 197 of Varre et al. lists a database comprising two sequences of RNA: a target sequence and a source sequence. Figure 1 of Varre et al. labels by letters, brackets, and dashes alongside each sequence sequential subsequences or a plurality of adjacent and subsequent nucleotides within the second sequence that occur within the first sequence. All of the nucleotides, whether in the first sequence, in the second sequence, labeled with bracketed alphabetic letters, or not labeled are stored as a unit in the sequence database of Figure 1 of Varre et al. Since every nucleotide of each sequence of Figure 1 of Varre et al. is stored in the database of Figure 1 of Varre et al., this database encompasses sets of nucleotides that are not within the first nucleic acid sequence. Furthermore, the entire list of sequences in Figure 1 of Varre et al. comprises the sum of each of the sequences. The bracketed subsequences of the sequences in Figure 1 of Varre et al. are interpreted to be "words" present in both sequences. Since the letters are "numbered" from a to k, there are a total of eleven words common to both sequences. The degree of common words between each of the sequences suggests the degree of difference or distance between to the two sequences in Figure 1 of Varre et al.

However, the article of Varre et al. does not show summing, combining, and differencing of sequences by inserting and deleting subsequences into sequences as required in view of the interpretation of the indefiniteness rejection described above. Additionally, the article of Varre et al. does not teach the computer limitations of the rejected claims.

The article of Queen et al. studies a comprehensive sequence analysis program for the IBM personal computer [title]. Specifically, Queen et al. uses an IBM personal computer to analyze biological sequences that include nucleic acid sequences [abstract]. In accomplishing this goal, the first paragraph on page 588 of Queen et al. describes deleting and inserting regions into sequences.

With regard to claims 7-9 and 17, as explained above, Figure 1 of Varre et al. comprises the sum of each of the sequences. The bracketed subsequences of the sequences in Figure 1 of Varre et al. are interpreted to be "words" present in both sequences. Since the letters are "numbered" from a to k, there are a total of eleven words common to both sequences. The degree of common words between each of the sequences suggests the degree of difference or distance between the two sequences in Figure 1 of Varre et al.

With regard to claims 3-5, all of the subsequences labeled with brackets have more than two sequential nucleotides in a row that are common between the two nucleotide sequences.

With regard to claim 6, as explained above, since every nucleotide of each sequence of Figure 1 of Varre et al. is stored in the database of Figure 1 of Varre et al., this database encompasses sets of nucleotides that are not within the first nucleic acid sequence (which comprises more than two nucleotide bases in a row).

With regard to claims 15 and 21, as explained above, the bracketed subsequences in Figure 1 of Varre et al. each have a plurality of bases (all brackets comprise more than two bases) in a sequential row that are common to both sequences. Figure 1 of Varre et al. itself is a database containing every base in both sequences.

It would have been obvious to someone of ordinary skill in the art at the time of the invention to modify the sequence database analysis of Varre et al. by use of the insertion and deletion of sequences into larger sequences as in Queen et al. wherein the motivation would have been that the modification of sequences by inserting and deleting sequences provides a user-accessible and *in silico* means for editing sequence data to incorporate useful subsequences and to dispose of unnecessary subsequence data [see first full paragraph on page 588 of Queen et al.].

It would have been obvious to someone of ordinary skill in the art at the time of the invention to modify the sequence database analysis of Varre et al. by use of the IBM

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computer of Queen et al. wherein the motivation would have been that automating the sequence analysis yields more expeditious processing of data [title and abstract].

Response to arguments:

Applicant's arguments filed 27 July 2010 have been fully considered but they are not persuasive.

Applicant argues on pages 11-12 of the Remarks that Varre et al. does not teach storing the nucleotides of the second sequence "as a unit." This argument is not persuasive because, absent a definition that "as a unit" signifies that the second sequence is stored together and separate from the other nucleotide data, the sequence in Figure 1 of Varre et al. is interpreted to comprise the second nucleotide data stored as a unit within the nucleotide sequence data.

Applicant next argues that the alleged interpretation of Queen et al. of determining the differences between words in a sequence is equivalent to removing a subsequence from a sequence is not correct. Instead, applicant argues that the meaning of determining a difference refers to removing a word from a pool of words. This argument is not persuasive because pages 6-7 of the specification teaches that taking a product between sequence P and sequence Q (i.e. forming sequence PQ) involves appending sequence Q to sequence P. It is noted that this rejection is an obviousness prior art rejection, and taking a product of two quantities is an obvious variant of summing them. Consequently, removing a subsequence from a sequence

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(taking a “quotient” as in Queen et al.) is an obvious variant of subtracting a sequence from a pool of sequences.

The following rejection necessitated by amendment:

35 U.S.C. 103 Rejection #2:

Claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varre et al. in view of Queen et al. as applied to claims 1, 3-11, 15, 17-19, and 21-23 above, in further view of Ono [US Patent 7,080,320 B2; issued 18 July 2006; filed 25 January 2002].

Claims 24-30 involve using different mathematical manipulations to determine the distances between sets of nucleotide sequences.

Varre et al. and Queen et al. make obvious determining distances using a family of dissimilarity measures in oligonucleotide sequences involving adding and discarding subsequences, as discussed above. Figure 1 of Varre et al. comprises the sum of each of the sequences. The bracketed subsequences of the sequences in Figure 1 of Varre et al. are interpreted to be “words” present in both sequences. Since the letters are “numbered” from a to k, there are a total of eleven words common to both sequences. The degree of common words between each of the sequences suggests the degree of difference or distance between to the two sequences in Figure 1 of Varre et al.

Varre et al. and Queen et al. do not teach the mathematical manipulations required to determine distances between nucleotide sequences.

Ono studies a method for analyzing translations by comparing and English article to the English translation of the article in a foreign language [title, abstract, and Figure 4 of Ono]. Specifically, Figure 4 of Ono illustrates the mathematical comparison of calculating similarity degrees (a measure of distance) between the English translation of a foreign article and the English article. More specifically, the equation in column 6 of Ono teaches summing the occurrences of each word in the both the English and English translations of a foreign (in this study, Japanese) articles and normalizing this sum by a squared quantity of the total number of co-occurrences of all of the terms in the English article and the English translation of the Japanese article. The result of this computation is an indication of the similarity between the English article and the English translation of the Japanese article.

Consequently, Ono teaches using dictionaries corresponding to the words in the English article and English translation of the Japanese article. As stated above, similarities are determined from the number of words in the English article dictionary that are also English translation of the Japanese article and the number of words in the dictionary of the English translation of the corresponding Japanese article that are in the original English article. Since these are "binary functions" (either the word is present OR the word is absent), these similarity distances are deducible from the number of words in the English article dictionary that are NOT in English translation of the Japanese article and the number of words in the dictionary of the English translation of the corresponding Japanese article that are NOT in the original English article. The sums in equation in column 6 of Ono take into account all of the co-occurrences (it

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represent maximum numbers of occurrences), and normalizes these co-occurrences by the co-occurrences of ALL of the terms. Since the total number of words are known (K) in the summations in column 6 of Ono, these summations are obvious variants of averages. Additionally, when analyzing the corpuses of the entire English article and English translation of the Japanese article (as in the denominator of the equation in column 6 of Ono), the corpuses of both articles, when taken together, represent the third and fourth sequences (depending on the order in which the articles are joined).

It would have been obvious to someone of ordinary skill in the art at the time of the invention to modify the sequence database analysis of Varre et al. and the insertion and deletion of sequences into larger sequences as in Queen et al. by use of the quantitative similarity calculation between sequences (or words) in Ono wherein the motivation would have been that while Ono applies the sequence similarity logic of Varre et al. and Queen et al. to determine distances between original and translated articles, Ono is automatically determining the a quantitative value for the quality of the translated document [abstract of Ono]. There would have been a reasonable expectation of success in applying the sequence matching algorithms for “biological” nucleotide sequences of Varre et al. and Queen et al. to the literary analysis of Ono because the “biological” analysis of sequence information of Varre et al. and Queen et al. are generally applicable to any type of sequence analysis; there is no recitation of any biological application to this sequence analysis besides determining sequence similarities.

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Response to arguments:

This rejection is newly applied.

The following rejection necessitated by amendment:

35 U.S.C. 103 Rejection #3:

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Varre et al. in view of Queen et al. in view of Ono as applied to claims 1, 3-11, 15, 17-19, and 21-30 above, in further view of Barbara et al. [US Patent 5,710,916; issued 20 January 1998].

Claim 31 is further limiting comprising determining a distance between the first and second sequences based on a distance measure that satisfies the triangle inequality.

Varre et al., Queen et al., and Ono make obvious determining similarity measures and distances between series of sequences, As discussed above.

Varre et al., Queen et al., and Ono do not teach finding distances in a manner that satisfies the triangle inequality.

The document of Barbara et al. studies finding the distance between two handwritten strings in a database [abstract].

Specifically, column 9, line 62 to column 10, line 10 of Barbara et al. teaches that it is important for the distance measurements to satisfy the triangle inequality.

It would have been obvious to someone of ordinary skill in the art at the time of the invention to modify the sequence database analyses of Varre et al., Queen et al.,

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and Ono by use of the calculation of distances that maintains the triangle inequalities as in Barbara et al. wherein the motivation would have been that maintaining the triangle inequality in distance calculations adds to the integrity and validity of the distance calculations [column 16, lines 38-45 of Barbara et al.]. Again, there would have been a reasonable expectation of success in applying the sequence matching algorithms for “biological” nucleotide sequences of Varre et al. and Queen et al. to the literary analyses of Ono and Barbara et al. because the “biological” analysis of sequence information of Varre et al. and Queen et al. are generally applicable to any type of sequence analysis; there is no recitation of any biological application to this sequence analysis besides determining sequence similarities.

Response to arguments:

This rejection is newly applied.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 8:30 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Russell S. Negin/
Examiner, Art Unit 1631
11 October 2010